

REMARKS

The Office Action of December 3, 2007, presents the examination of claims 19 and 20, claims 21-30 being withdrawn pursuant to a restriction requirement. Claims 21-30 are canceled. New claims 31 and 32 are added. Claims 19, 20, 31 and 32 are now pending in the application.

Claim 19 is amended to recite that the antibody is one that blocks a biological activity of CD81. Support for such amendment is provided in the specification at least at the last three lines of page 7 of the specification, taken with page 8, lines 5-8.

New claim 31 is directed to the form in which the antibody is administered. Support for new claim 31 is provided by the specification at least at page 48.

New claim 32 recites a physiological effect of the treatment, which is described in the specification in Example 5, and particularly at the paragraph bridging pp. 101-102.

Objection to the specification

The Examiner objects to the specification because of an embedded hyperlink; the examiner particularly points out taxed at page 12, first four paragraphs on page 13, third paragraph. The specification is amended to delete the embedded hyperlinks. References instead made to the website. No new matter is added by the amendments to the specification.

Rejection under 35 USC § 112, first paragraph

Claims 19 and 20 stand rejected under 35 USC § 112, first paragraph, for alleged lack of enablement of the claimed invention. In essence, the examiner's explanation of the ground of rejection relates to a lack of showing in the specification of "prevention" of inflammatory bowel disease (IBD). The term "preventing" is removed from the claims, thus obviating this ground of rejection.

Rejection under 35 USC § 102

Claims 19 and 20 are rejected under 35 USC § 102(b.) as being anticipated by US 6423501 or alternatively by WO 98/25647. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that both references teach that an agent which induces CD81 mediated signal transduction can be used for treating inflammatory diseases such as IBD and that said agent may be a polyclonal or monoclonal antibody, such as an anti-CD81 antibody. The Examiner emphasizes that the claims as presented encompass any anti-CD81 antibody.

Applicants submit that the present claims are distinguishable from the teachings of the cited references. In particular, the claims recite that the anti-CD81 antibody is one that "blocks a biological activity of CD81".

Example 4 of the instant specification demonstrates that CD81 is a pathogenic state determinant or marker in T cells and is a pathogenic factor which causes and advances the pathogenic state of IBD. In addition, Example 5 confirmed that the IBD model animal was duly improved and treated by the administration of an anti-CD81 antibody. The antibody used in this Example is Clone 2F7 manufactured by Southernbiotech. Attached hereto is a copy of the company catalogue page describing this antibody, which is described as an antibody that blocks thymocyte interaction with CD81 *in vitro*.

In contrast, as the Examiner indicated, the cited references teach that agents for treating IBD can be anything which binds to or interacts with CD81 and induces (i.e. activates) or enhances CD81-mediated signal transduction. The anti-CD81 antibody which can be used in US '501 or WO '647 patent must activate or enhance a biological effect of CD81, and therefore are different from the antibody recited in claim 19. Indeed, the cited references teach away from the instant invention, which reflects that inhibiting a biological activity of CD-81 provides a therapy for treatment of IBD.

Thus, the present invention is clearly distinct from the disclosure of the references cited by the Examiner, and so the instant rejections for lack of novelty should be withdrawn.

Conclusion


Applicants submit that the claims present well-described subject matter that is free of the prior art. The favorable actions of withdrawal of the present rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D. Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By 
Mark J. Nuell

Registration No.: 36,623
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive
Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant